UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF SUSAN BAIN

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INTRODUCTION

Plaintiffs' opposition seeks to rewrite Dr. Susan Bain's CV and her deposition testimony, blame her ignorance of basic regulatory and scientific concepts on defense counsel's questioning and trivialize her inaccurate responses to those questions as "inconsequential." In so doing, plaintiffs have confirmed that Dr. Bain is not competent to serve as an expert in this case and that her opinions should be excluded in their entirety.

First, plaintiffs effectively concede that Dr. Bain's brief tenure as a junior employee at the FDA – where her work involved veterinary drugs and medical devices – is irrelevant to her proffered regulatory expertise, and devote their discussion of Dr. Bain's private sector experience to downplaying the gross and repeated misrepresentations of the extent of that experience on her CV (e.g., her interactions with the FDA) as "minute" and "hyper-technical." But these misstatements are not a trivial matter; rather, they call into question the entirety of Dr. Bain's regulatory experience. This is all the more true given Dr. Bain's inability to answer basic questions about ICH guidelines and FDA regulations, which plaintiffs unfairly blame on defense counsel's questioning or try to explain away with after-the-fact explanations that Dr. Bain never expressed.

Second, plaintiffs also fail to identify what (if any) relevant experience or credentials Dr. Bain has that remotely qualify her to opine on the science-based

manufacturing processes that comprise a significant portion of her report. Instead, they focus their attention on either minimizing Dr. Bain's erroneous responses as "inconsequential" or claiming that defense counsel somehow prevented Dr. Bain from consulting her report. But Dr. Bain's lack of knowledge about such basic information as the testing methodology she claims ZHP should have employed before 2018 or the IARC monograph she repeatedly invoked at her deposition cannot be justified by leveling baseless attacks on defense counsel, who never precluded Dr. Bain from consulting her report. Nor can Dr. Bain compensate for her science-based ignorance by parroting the opinions of plaintiffs' other experts, having disclaimed any "attempt to assess the validity" of those opinions. *In re TMI Litig.*, 193 F.3d 613, 714-16 (3d Cir. 1999) (cited in Opp'n at 23).

Third, even if Dr. Bain were qualified to offer any of the regulatory or science-based opinions in her report, plaintiffs essentially concede that she did not consider evidence that was favorable to defendants' position, a telltale indicator of an unreliable methodology; they do not dispute that many of Dr. Bain's opinions are improper legal conclusions; and while they promise that Dr. Bain will not simply "regurgitate facts to the jury," significant portions of her report do just that.

For all of these reasons, discussed in greater detail below, the Court should exclude Dr. Bain's opinions in full.

ARGUMENT

I. DR. BAIN IS NOT QUALIFIED TO TESTIFY IN THIS CASE.

Although plaintiffs argue that Dr. Bain satisfies the Third Circuit's "liberal[]" qualifications requirement (Opp'n at 5), "every proffered witness is ***not*** qualified as an expert," *Campione v. Kivatisky*, No. 09-2019, 2011 U.S. Dist. LEXIS 78329, at *11-12 (D.N.J. July 19, 2011) (emphasis added). Rather, "Rule 702 requires a witness to have 'specialized knowledge' regarding ***the area of testimony***" on which she seeks to opine. *Id.* (emphasis added); *see also Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1055-56 (3d Cir. 1997) ("Although the Rule mandates a policy of liberal admissibility . . . we agree with the district court that Brink did not qualify" where he did not "possess[] sufficient knowledge of the phenomenon of habituation," which "was the crux of his theory of liability"). Here, Dr. Bain's opinions should be excluded because she has no specialized knowledge regarding API manufacturers, the regulations that govern them and the science behind the two manufacturing processes discussed in her report.

A. Dr. Bain Is Not Qualified To Offer Her Regulatory Opinions.

1. Dr. Bain lacks the requisite experience to serve as a regulatory expert in this case.

Plaintiffs do not dispute that Dr. Bain's limited FDA experience at a junior level, in an unrelated field, does not qualify her to serve as an expert on the

regulatory requirements applicable to API drug manufacturers.[1] And the closest plaintiffs come to arguing that Dr. Bain's private sector experience – including at generic manufacturer Watson – qualifies her as an expert is their attempt to downplay the misrepresentations on Dr. Bain's CV as "minute" and "hyper-technical." (Opp'n at 12, 13.) For example, plaintiffs do not seriously dispute that Dr. Bain misrepresented the extent of her interactions with the FDA on her CV; instead, they contend that the "[q]uantity" of such communications "is not a requirement to be qualified." (*Id.* at 12.) In so arguing, however, plaintiffs are missing the point of defendants' argument, which is that Dr. Bain exaggerated the extent of those interactions – which "raise[s] serious concerns as to whether [Dr. Bain's] expert report accurately reflects h[er] qualifications." *Balimunkwe v. Bank of Am.*, No. 14-cv-327, 2015 WL 5167632, at *8 (S.D. Ohio Sept. 3, 2015), *report and recommendation adopted*, 2015 WL 5836975 (S.D. Ohio Oct. 2, 2015).

Nor can plaintiffs explain away these glaring misstatements by rewriting Dr.

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[1] Plaintiffs' treatment of Dr. Bain's brief "time at the FDA" is limited to a couple of sentences acknowledging that her experience "primarily related to medical devices, and also veterinary drugs" (Opp'n at 12), which cannot be compared to the 10-year experience deemed insufficient in defendants' cited authority. *See Ghorley v. Baxter Healthcare Corp.*, No. 17-cv-3091, 2019 WL 13240522, at *6 (N.D. Ga. Sept. 9, 2019) (cited in Mem. at 8, 9). Moreover, while plaintiffs assert that the proposed expert in *Ghorley* had conceded "that he [was] not familiar with regulations that govern medical devices" (Opp'n at 17 (citation omitted)), that case turned on the fact that the proposed expert's "***pharmaceutical***" experience at the FDA "ha[d] nothing to do with the regulation, label, or manufacture of medical ***devices***," 2019 WL 13240522, at *6 (emphases added). The same logic applies here.

Bain's CV or twisting her deposition testimony. Plaintiffs argue that Dr. Bain's testimony that she only had limited interactions with the FDA is consistent with her CV because her "primary roles have been mostly dedicated to internal quality activities, not regulatory affairs." (Opp'n at 13.) But the CV represents that Dr. Bain ***herself*** "[i]nterfaced with [the] FDA regarding cGMP audits and compliance issues" while at SpineWorks, LLC (Bain CV at 3 (ECF 2284-3, Ex. A)), served as an "interface with [the] FDA for product recalls and recall releases" while at Watson (*id.* at 4), and "***managed*** FDA Communication and MDR submissions" while at Porex Medical Products. (*Id.* (emphasis added).) The import of these repeated statements on Dr. Bain's CV is that she was directly responsible for communicating with the FDA – a claim that Dr. Bain's deposition testimony definitively establishes is false.

Unable to point to any relevant FDA or private sector experience, plaintiffs argue that Dr. Bain is qualified by virtue of her "education and academic work," which included taking and teaching classes on both "drugs" and medical devices and writing a book "chapter on drugs" and her "consult[ing] for human drug manufacturers." (Opp'n at 8-12.) But none of this general experience reflects any "'specialized knowledge' regarding the area of testimony" Dr. Bain seeks to offer at trial, *Campione*, 2011 U.S. Dist. LEXIS 78329, at *11-12 – i.e., the regulatory requirements applicable to API manufacturers. Although plaintiffs assert that Dr.

Bain need not have "direct involvement in the manufacture of API" (Opp'n at 7), defendants' point is that Dr. Bain has zero ***knowledge, experience or credentials*** regarding that subject, much less the regulation of API manufacturers. Indeed, Dr. Bain expressly disclaimed having such expertise at her deposition (*see* Bain Dep. 120:3-11 (ECF 2284-4) (making clear that her "expertise is ***not*** in the area of API" manufactures) (emphasis added)), rendering her general academic or educational background regarding pharmaceutical drugs impertinent.

Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 658 (E.D. Pa. 2012) (cited in Opp'n at 7), is inapposite. In that case, the court reasoned that a doctor who "worked for the FDA for twenty years" in the area of "drug safety" and "regulatory science," another doctor who wrote a citizen's petition to the FDA "engag[ing] extensively with the relevant FDA regulations" at issue in the case, and an "experienced pharmacologist and toxicologist [who] . . . taught graduate students and FDA employees about FDA regulations" all could testify about pharmaceutical manufactures' compliance with FDA regulations. *Id.* at 658-59. Dr. Bain's experience is not remotely comparable.

2. Dr. Bain demonstrated a lack of basic regulatory competency at her deposition.

As explained in defendants' opening brief, Dr. Bain's lack of any grasp of basic regulatory concepts and principles separately "demonstrates [that she] lacks competency to" testify about them. *See Dreyer v. Ryder Auto. Carrier Grp., Inc.*,

367 F. Supp. 2d 413, 428 (W.D.N.Y. 2005) (cited in Mem. at 7). Plaintiffs assert that the expert in *Dreyer* refused to answer questions on the ground that they "w[ere] beyond the scope of the deposition" (Opp'n at 16 (citation omitted)), but the court clearly held that "an expert who is incapable of explaining forthrightly basic concepts within his claimed area of expertise . . . at a deposition is not competent to offer testimony to the jury on such matters," *Dreyer*, 367 F. Supp. 2d at 428. That is the same infirmity that plagues Dr. Bain's opinions. Although plaintiffs attempt to blame Dr. Bain's lack of understanding on defense counsel's purportedly "elusive questioning" (Opp'n at 17), the transcript shows that counsel merely asked for basic information about the ICH guidelines and FDA regulations that ***Dr. Bain*** repeatedly discusses in her report – e.g., what they "cover" and what they "apply" to. (*See, e.g.*, Bain Dep. 157:10-23.)

To the extent plaintiffs attempt to defend Dr. Bain's responses to counsel's questioning, they do so by either rewriting her testimony or minimizing her answers as "irrelevant." For example, plaintiffs contend that Dr. Bain's testimony regarding the significance of ICH guidelines is "substantively accurate" because she acknowledged that "[g]uidance documents do not establish legally enforceable rights or responsibilities." (Opp'n at 18 (citation omitted).) But Dr. Bain went on to testify that the guidance is "considered to be ***binding***,'" (*id.* (emphasis added) (citation omitted)) – which is the nub of her opinion and is contrary to law. 21 C.F.R.

§ 10.115(d)(1). Plaintiffs also try to minimize Dr. Bain's conflation of ICH Q8 with ICH Q11 on the ground that any variance between the two "is a distinction without a difference." (Opp'n at 19.) But that not only flies in the face of the plain language of the two guidelines (the former addresses the suggested content for the pharmaceutical development section of a regulatory submission, while the latter addresses the pharmaceutical development process itself, *compare* FDA Q8(R2) § 1.1, *with* ICH Q11 § 1), it also defies logic since it would render ICH Q11 entirely superfluous. And although plaintiffs claim that Dr. Bain's testimony that ICH Q9 addresses "[q]uality systems" (Bain Dep. 159:7-15) is accurate because that guideline refers in passing to "quality systems," Dr. Bain's own report makes clear that this topic is addressed by ICH Q10 (*see* Bain Rep. at 4 (ECF 2284-3)).[2] In short, plaintiffs' defense of Dr. Bain's ICH-related knowledge is itself contrary to the plain language of the ICH guidelines.

Plaintiffs also assert that Dr. Bain was correct to testify that 21 C.F.R. § 210.1(a) and 21 C.F.R. § 211.1(b) apply to API manufacturers notwithstanding their plain language because defendants' own class-certification expert, David Chesney,

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[2] Notably, Dr. Bain did not provide any of these explanations at her deposition. *See Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672-73 (6th Cir. 2010) (rejecting counsel's effort to redefine the expert's opinion; the expert's "opinion cannot escape its own logic"); *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 667 (D.N.J. 2008) ("If Dr. Parisian was unable to explain why these studies help inform her conclusion regarding the ability of bone allografts to transmit disease, [p]laintiffs' counsel cannot fill in the gaps.").

previously testified as much. (Opp'n at 21-22.) Not so. Dr. Chesney explicitly testified that "GMP regulations at 21 CFR Part 211 may be used to guide an FDA Investigator's thinking, but only the statutory ***concept*** of GMP is enforcement, not the specific wording of the ***regulations***." (Chesney Rep. at 51 (emphases added) (ECF 2038-7).) Plaintiffs also contend that Dr. Bain's lack of basic knowledge of the FDA itself (e.g., whether the FDA has organic chemists, whether the FDA has a department of chemistry and who actually reviews Drug Master Files) and unawareness of what (if any) regulatory actions the FDA took with respect to ZHP's VCDs prior to 2018 are "irrelevant" to "her opinions about ZHP's conduct" and would likely be excluded on a motion in limine. (Opp'n at 22.) But that is not the point; the point is that Dr. Bain has no knowledge of the area on which she seeks to opine, and this testimony bears directly on Dr. Bain's so-called expertise to opine that ZHP's conduct "violated" FDA regulations. (*See* Bain Rep. at 1.) In short, nothing in plaintiffs' opposition changes the fact that Dr. Bain lacks both the experience and relevant understanding to serve as a regulatory expert in this case.

B. Dr. Bain Is Not Qualified To Offer Her Science-Based Opinions.

1. Dr. Bain lacks the experience and knowledge to opine about chemical reactions.

Plaintiffs do not identify any relevant academic or professional experience that remotely qualifies Dr. Bain to opine on the scientific intricacies behind ZHP's manufacturing processes. Instead, plaintiffs argue that Dr. Bain's ignorance of the

"technical differences" between the two testing methodologies discussed in her report is irrelevant because "[t]he key is that she understands [that] the correct technology was available and ultimately was used to identify the contaminants." (Opp'n at 24.) But it is precisely Dr. Bain's lack of knowledge of those complex methodologies that renders her woefully unqualified to opine that one testing methodology should have been used as opposed to the other. (*See* Bain Rep. at 72.) Similarly, although plaintiffs contend that Dr. Bain's "error" in describing the IARC monograph as supposedly stating that DMF can degrade into dimethylamine was "inconsequential" (Opp'n at 25), it was in fact a fundamental mistake that undermines the entire basis for Dr. Bain's claim that ZHP's risk assessment was inadequate and highlights that she does not understand "basic concepts" underlying her opinions, *see Dreyer*, 367 F. Supp. 2d at 428, and simply tried to echo the opinions of plaintiffs' counsel.

Plaintiffs also argue that Dr. Bain's inability to correctly answer questions was the fault of defense counsel, but that is both disingenuous and factually untrue. For example, plaintiffs claim that when defense counsel questioned Dr. Bain about the phrase "high potency genotoxic," she did not "let[] her see where the phrase . . . appeared in her report and what it was describing" (Opp'n at 24), ignoring that it was ***plaintiffs' counsel*** who repeatedly referred to that phrase in quoting from Dr. Bain's report and leading the witness to state (without any explanation) that ZHP did

not undertake adequate risk assessments (*see* Bain Dep. 239:19-240:10). In any event, defense counsel never precluded Dr. Bain from "consult[ing]" her report. (Opp'n at 24.) Rather, she told the witness that "[i]f you're going to be reading your report for more than a few minutes, the [rule] in this litigation is, we go off the record." (Bain Dep. 129:19-21.) Dr. Bain repeatedly did just that and was still unable to answer the questions posed to her. (*See id.* 128:21-129:24 (noting two "pause[s] in the proceedings" while Dr. Bain reviewed her report for relevant information and still testified "I just can't answer that. I'm sorry.").) In sum, the excuses provided in plaintiffs' opposition only reinforce Dr. Bain's lack of competency to weigh in (much less offer "expert" opinions) on these technical matters.

2. Dr. Bain inappropriately parrots the conclusions of plaintiffs' other experts.

Plaintiffs' opposition brief also confirms that Dr. Bain's science-based opinions are really those of plaintiffs' other experts (or plaintiffs' counsel themselves), further highlighting her lack of expertise on these topics. Plaintiffs assert that "[a]n expert may rely on other subject matter experts ***as long as the expert 'attempt[s] to assess the validity*** of any of the assumptions the other experts used to formulate their opinions.'" (Opp'n at 23 (emphasis added) (quoting *TMI*, 193 F.3d at 714-16).) But in *TMI*, plaintiffs' own cited case, the Third Circuit affirmed the exclusion of a witness's testimony precisely because he "***fail[ed]***" to undertake that essential step. 193 F.3d at

716 (emphasis added). Dr. Bain engaged in the same type of improper parroting here, expressly testifying that she did not "personally test" the assumptions underlying the reports of Drs. Hecht and Najafi (Bain Dep. 82:1-12), which renders her a mere "mouthpiece" of those other experts, *Torain v. City of Philadelphia*, No. 14-1643, 2023 WL 174952, at *5 (E.D. Pa. Jan. 12, 2023) (citation omitted).[3]

Plaintiffs again assert that Dr. Bain is only doing what ZHP's experts (Dr. Chesney and Dr. Afnan) have done in relying on other experts (Opp'n at 23-24), but the testimony they cite from Dr. Chesney merely states that ***if he had been shown*** information that "ZHP knew . . . there was NDMA in the valsartan . . . it would have raised certain questions in [his] mind," which he would have "referred . . . to [the] subject matter experts" (Chesney Dep. 221:24-223:1 (ECF 2038-3)). And Dr. Afnan – who possesses degrees in chemistry – looked at the materials Dr. Xue referenced and "verif[ied]" that certain of his statements on the relevant chemistry were correct. (Afnan Dep. 155:20-158:13 (ECF 2286-2, Ex. 1).) Dr. Bain did nothing of the sort.

[3] Plaintiffs argue that, unlike in *Torain*, Dr. Bain's report was not "a clear copy and paste" of another expert's "report from a separate litigation." (Opp'n at 25 (quoting *Torain*, 2023 WL 174952, at *5).) But *Torain* more broadly held that "[e]xperts may not simply 'parrot' the ideas of other experts," 2023 WL 174952, at *5 – which is what Dr. Bain did in this case by "[b]as[ing] [her science-based opinions] on the reports of . . . Drs. Hecht and Najafi" without any assessment of the soundness of those reports (Bain Dep. 82:1-12).

II. DR. BAIN'S OPINIONS ARE NOT BASED ON A RELIABLE METHODOLOGY AND DO NOT CONSTITUTE PROPER EXPERT EVIDENCE.

A. Dr. Bain's Opinions Are Not Based On A Reliable Methodology.

Plaintiffs also argue that ZHP is challenging conclusions, not methodology. But the issue here is not the correctness of plaintiffs' expert's ultimate conclusions; it is whether those conclusions are based on a reliable methodology. They are not, because as plaintiffs concede, Dr. Bain ignored audits performed by ZHP customers and portions of fact testimony that undermine plaintiffs' theory of liability. (Opp'n at 27-28.) Plaintiffs contend that the customer audits are "inadmissible to prove that the cGMP violations did not occur" (*id.* at 28), but the audits would plainly be relevant to ZHP's notice, *see In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 18-cv-01320, 2021 WL 5881793, at *3-4 (S.D. Ohio Dec. 13, 2021), and even if they were not, that would be no excuse for Dr. Bain's failure to consider that information in formulating her opinions, *see* Fed. R. Evid. 703. Plaintiffs' excuse that the fact testimony Dr. Bain omitted from her review is "self-serving" (Opp'n at 28), is even more illogical because, as their own authority instructs, an expert is supposed to "'present a balanced analysis' and point[] out [evidence] on both sides of the issue," *Glynn v. Merck Sharp & Dohme Corp.*, Nos. 11-5304, 08-08, 2013 WL 1558690, at *2 (D.N.J. Apr. 10, 2013)

(citation omitted) (cited in Opp'n at 26).[4]

B. Certain Of Dr. Bain's Opinions Are Improper Legal Conclusions.

Plaintiffs do not dispute that certain of Dr. Bain's opinions (e.g., that ZHP "violated" certain legal obligations) constitute improper legal conclusions. Rather, they contend that defendants' argument is "premature" because it does not implicate *Daubert*. (Opp'n at 29.) But this argument is foreclosed by the Court's prior *Daubert* ruling, which excluded Dr. Najafi's opinion regarding bioequivalence on the ground that it "wade[d] too far into the factfinder's domain." (Class Certification Ruling at 91 (ECF 2261).)

C. Dr. Bain's Factual Narratives Are Also Improper.

Finally, plaintiffs promise that Dr. Bain "is not going to simply summarize and regurgitate facts to the jury" (Opp'n at 30), effectively conceding that such a tactic would be improper. Plaintiffs nonetheless appear to argue that the portions of Dr. Bain's report proposing to do precisely that do not implicate *Daubert* because defendants only cited cases applying this principle at the trial stage. (*Id.*) That is not true. Defendants cited authority excluding improper narrative opinions before

[4] This failure is all the more glaring in light of the circular nature of Dr. Bain's opinion that ZHP's risk assessments were inadequate because they did not uncover the presence of NDMA or NDEA. (*See* Bain Dep. 169:7-12.) Although plaintiffs claim that defendants are focusing on "an isolated answer" (Opp'n at 28), Dr. Bain ***repeatedly*** testified that ZHP's risk assessment was inadequate because "[t]hey didn't find it" (i.e., NDMA) (Bain Dep. 180:14-15; *see also id.* 188:2-5 (similar)).

trial on the ground that they inappropriately "summarize[d] documents or conversations." *Pritchett v. I-Flow Corp.*, No. 09-cv-02433, 2012 WL 1059948, at *7 (D. Colo. Mar. 28, 2012). Indeed, the very purpose of *Daubert* is for the Court to exercise its gate-keeping function and exclude improper expert evidence ***in advance of trial***. Accordingly, the Court should rule that Dr. Bain is not permitted to "summarize documents" that the jury is perfectly capable of understanding.

CONCLUSION

For the foregoing reasons, as well as those set forth in defendants' opening brief, the Court should exclude all of Dr. Bain's opinions in full.

Dated: April 25, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 25, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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